

# Reporting Adverse Reactions: **MedWatch Form FDA 3500A**

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**FDA**

Centers for Biologics Evaluation and Research (CBER)

Office of Biostatistics and Epidemiology

Therapeutics and Blood Safety Branch

# MedWatch and HCT/P Safety

- With MedWatch, FDA can detect trends across the country that may not be identified at an individual site.
- Goal of HCT/P surveillance is to prevent additional adverse reactions.

It is a reportable HCT/P  
adverse reaction, now what do I do?

- You have **15 days** from receipt of information
- Use Form FDA 3500A (MedWatch)

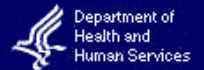
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[www.fda.gov/medwatch](http://www.fda.gov/medwatch) or [www.hhs.gov/forms](http://www.hhs.gov/forms)

# MedWatch forms: <http://www.fda.gov/medwatch/>



U.S. Food and Drug Administration



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**The FDA Safety Information and  
Adverse Event Reporting Program**

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Welcome to MedWatch, your Internet gateway for timely safety information on the drugs and other medical products regulated by the U.S. Food and Drug Administration.

## What's New

[Cordarone \(amiodarone HCl\)](#) - New Medication Guide issued, to be provided with each prescription dispensed to patients.  
(Posted 01/10/2005)

[Avastin \(bevacizumab\)](#) - WARNINGS, PRECAUTIONS, ADVERSE EVENTS, and DOSAGE AND ADMINISTRATION sections of labeling updated to describe arterial thromboembolic events when Avastin is used in combination with intravenous 5-fluorouracil-based chemotherapy.  
(Posted 01/06/2005)

[American Health & Herbs Ministry Eye Rinse Products](#) - Voluntary recall following FDA inspection which

## [Safety Information](#)



## [Medical Product Reporting](#)



# Reporting Adverse Reactions with MedWatch: Form FDA 3500A (3500 for Voluntary) Page 1

U.S. Department of Health and Human Services

**MEDWATCH**  
The FDA Safety Information and  
Adverse Event Reporting Program

For use by user-facilities,  
importers, distributors and manufacturers  
for MANDATORY reporting

Page \_\_\_\_ of \_\_\_\_

Form Approved 04-0114 No. 0035-0201 Expires 03/01/05  
See OMB statement at 32 CFR 1.105

ALL Report # \_\_\_\_\_  
CD Reporter Report # \_\_\_\_\_  
FDA Use Only

**A. PATIENT INFORMATION**

1. Patient Identifier \_\_\_\_\_  
In confidence

2. Age at Time of Event \_\_\_\_\_  
or \_\_\_\_\_  
Date of Birth \_\_\_\_\_

3. Sex ☐ Female ☐ Male

4. Weight \_\_\_\_\_  
lb or \_\_\_\_\_  
kg

**B. ADVERSE EVENT OR PRODUCT PROBLEM**

1. ☐ Adverse Event ☐ Product Problem (e.g., defect/malfunction)

2. Outcomes Attributed to Adverse Event (check all that apply)

☐ Death (priority) ☐ Disability

☐ Life-threatening ☐ Congenital Anomaly

☐ Hospitalization - initial or prolonged ☐ Required Intervention(s) Prevalent Period(s) Reported/Device(s)

☐ Other \_\_\_\_\_

3. Date of Event (priority/year) \_\_\_\_\_

4. Date of This Report (priority/year) \_\_\_\_\_

5. Describe Event or Problem \_\_\_\_\_

**C. SUSPECT MEDICATION(S)**

1. Name (give generic strength if not known, if known)

#1 \_\_\_\_\_

#2 \_\_\_\_\_

2. Dose, Frequency & Route Used

#1 \_\_\_\_\_

#2 \_\_\_\_\_

3. Therapy Dates (start/stop, give duration)  
Route (if not stated)

#1 \_\_\_\_\_

#2 \_\_\_\_\_

4. Diagnosis for Use (Indication)

#1 \_\_\_\_\_

#2 \_\_\_\_\_

5. Lot # (if known)

#1 \_\_\_\_\_

#2 \_\_\_\_\_

6. Exp. Date (if known)

#1 \_\_\_\_\_

#2 \_\_\_\_\_

7. Event Abated After Use Stopped or Dose Reduced?

#1 ☐ Yes ☐ No ☐ Don't Apply

#2 ☐ Yes ☐ No ☐ Don't Apply

8. Event Reappeared After Readministration?

#1 ☐ Yes ☐ No ☐ Don't Apply

#2 ☐ Yes ☐ No ☐ Don't Apply

9. NDC# (for product problems only)

#1 \_\_\_\_\_

#2 \_\_\_\_\_

10. Concurrent Medical Products and Therapy Dates (include treatment of event)

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**D. SUSPECT MEDICAL DEVICE**

1. Brand Name \_\_\_\_\_

2. Type of Device \_\_\_\_\_

3. Manufacturer Name, City and State \_\_\_\_\_

4. Model # \_\_\_\_\_

5. Lot # \_\_\_\_\_

6. Catalog # \_\_\_\_\_

7. Expiration Date (priority/year) \_\_\_\_\_

8. Serial # \_\_\_\_\_

9. Other # \_\_\_\_\_

10. Operator of Device

☐ Health Professional

☐ Lay User/Infant

☐ Other \_\_\_\_\_

11. If Reported, Give Date (priority/year)

#1 \_\_\_\_\_

#2 \_\_\_\_\_

12. If Reported, Give Date (priority/year)

#1 \_\_\_\_\_

#2 \_\_\_\_\_

13. Is this a Single-use Device that was Reprocessed and Reused on a Patient?

☐ Yes ☐ No

14. If Yes to Q13, Re-sterilization Date (priority/year) \_\_\_\_\_

15. Device Available for Evaluation? (Do not send to FDA)

☐ Yes ☐ No ☐ Returned to Manufacturer on \_\_\_\_\_ (priority/year)

16. Concurrent Medical Products and Therapy Dates (include treatment of event)

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**E. INITIAL REPORTER**

1. Name and Address \_\_\_\_\_

Phone # \_\_\_\_\_

2. Health Professional? ☐ Yes ☐ No

3. Occupation \_\_\_\_\_

4. Will Report/Also Send Report to FDA? ☐ Yes ☐ No ☐ Unk.

PLEASE TYPE OR USE BLACK INK

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

FDA

FORM FDA 3500A (9/03)

# MedWatch Form FDA 3500A

## Page 1

### Section A: Patient Information

### Section B: Adverse Event, Product Problem or Error

A. PATIENT INFORMATION			
1. Patient Identifier  In confidence	2. Age at Time of Event: or _____ Date of Birth: _____	3. Sex <input type="checkbox"/> Female <input type="checkbox"/> Male	4. Weight _____ lbs or _____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM	
1. <input type="checkbox"/> Adverse Event and/or <input type="checkbox"/> Product Problem (e.g., defects/malfunctions)	
2. Outcomes Attributed to Adverse Event (Check all that apply) <input type="checkbox"/> Death: _____ (mo/day/yr) <input type="checkbox"/> Life-threatening <input type="checkbox"/> Hospitalization - initial or prolonged	
<input type="checkbox"/> Disability <input type="checkbox"/> Congenital Anomaly <input type="checkbox"/> Required Intervention to Prevent Permanent Impairment/Damage <input type="checkbox"/> Other: _____	
3. Date of Event (mo/day/year)	4. Date of This Report (mo/day/year)
5. Describe Event or Problem	
6. Relevant Tests/Laboratory Data, Including Dates	
7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, smoking and alcohol use, hepatic/renal dysfunction, setting etc.)	

# MedWatch Form FDA 3500A Page 1

For HCTP's:

Use Section C  
for Suspect  
Medication(s)  
*not*

Section D for  
Suspect Device

C. SUSPECT MEDICATION(S)			
1. Name (Give labeled strength & manufacturer, if known)			
#1 _____			
#2 _____			
2. Dose, Frequency & Route Used		3. Therapy Dates (If unknown, give duration) from/to (or best estimate)	
#1 _____		#1 _____	
#2 _____		#2 _____	
4. Diagnosis for Use (Indication)		5. Event Abated After Use Stopped or Dose Reduced?	
#1 _____		#1 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply	
#2 _____		#2 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply	
6. Lot # (if known)	7. Exp. Date (if known)	8. Event Reappeared After Reintroduction?	
#1 _____	#1 _____	#1 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply	
#2 _____	#2 _____	#2 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply	
9. NDC# (For product problems only)			
- -			
10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)			
D. SUSPECT MEDICAL DEVICE			
1. Brand Name			
2. Type of Device			
3. Manufacturer Name, City and State			
4. Model #	Lot #	5. Operator of Device	
Catalog #	Expiration Date (mo/day/yr)	<input type="checkbox"/> Health Professional	
Serial #	Other #	<input type="checkbox"/> Lay User/Patient	
6. If Implanted, Give Date (mo/day/yr)		<input type="checkbox"/> Other: _____	
7. If Explanted, Give Date (mo/day/yr)			
8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?			
<input type="checkbox"/> Yes <input type="checkbox"/> No			
E. INITIAL REPORTER			
1. Name and Address		Phone #	
2. Health Professional?		3. Occupation	4. Initial Reporter Also Sent Report to FDA
<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unk.



# Filling out Section C. for an HCT/P

C1. Name, manufacturer

C3. Dates of Use:

#1 *Date of implant*

#2 *Date of explant, if applies*

C4. Diagnosis or Reason  
for use

C6. Lot #

C7. Expiration #

C10. Concomitant  
Medical Products

C. SUSPECT MEDICATION(S)		Section C - Help
1. Name (Give labeled strength & mfr/labeler, if known)		
#1	Tibialis Tendon      Jointsave Company	
#2		
2. Dose, Frequency & Route Used		3. Therapy Dates (If unknown, give duration from/to (or best estimate))
#1		#1 11/9/04
#2		#2 11/30/04
4. Diagnosis for Use (Indication)		5. Event Abated After Use Stopped or Dose Reduced?
#1	ACL repair	#1 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply
#2		#2 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply
6. Lot # (if known)	7. Exp. Date (if known)	8. Event Reappeared After Reintroduction?
#1 AZ2004-1264	#1 08/05	#1 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply
#2	#2	#2 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply
9. NDC# (For product problems only)		
10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)		
Cephalexin 500 mg po bid 11/23-11/30/04		

(C2, C5, C8, C9 are not relevant for HCT/P's)



# Proposed MedWatch 3500A

*Changes in this section:*

Section D.  
Suspect **PRODUCT(S)**

**D9. NDC# or Unique ID**

			FDA Use Only
<b>D. SUSPECT PRODUCT(S)</b>			
1. Name, strength, manufacturer <i>(from product label)</i>			
#1 _____			
#2 _____			
2.	Dose or Amount	Frequency	Route
#1	_____	_____	_____
#2	_____	_____	_____
3. Dates of Use <i>(If unknown, give duration) from/to (or best estimate)</i>		5. Event Abated After Use Stopped or Dose Reduced?	
#1 _____		#1 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply	
#2 _____		#2 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply	
4. Diagnosis or Reason for Use <i>(Indication)</i>		8. Event Reappeared After Reintroduction?	
#1 _____		#1 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply	
#2 _____		#2 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply	
6. Lot #	7. Expiration Date		9. NDC # or Unique ID
#1 _____	#1 _____		
#2 _____	#2 _____		
<b>E. SUSPECT MEDICAL DEVICE</b>			

## Section E.

Initial Reporter  
(who reported to  
you)

E. INITIAL REPORTER		
1. Name and Address		Phone #
2. Health Professional? <input type="checkbox"/> Yes <input type="checkbox"/> No	3. Occupation	4. Initial Reporter Also Sent Report to FDA <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unk.

# MedWatch Form FDA 3500A

## Page 2

**Section F:**  
For Use by User  
Facility/Importer  
(Devices Only)

**Section G:**  
All Manufacturers

**Section H:** Device  
Manufacturers

### Medication and Device Experience Report

(Continued)

Refer to guidelines for specific instructions

Submission of a report does not constitute  
an admission that medical personnel, user  
facility, importer, distributor, manufacturer or  
product caused or contributed to the event.

Page \_\_\_\_ of \_\_\_\_

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Public Health Service • Food and Drug Administration

RECEIVED

F. FOR USE BY USER FACILITY/IMPORTER (Devices Only)			
1. Check One <input type="checkbox"/> User Facility <input type="checkbox"/> Importer		2. LR Report/Report Number	
3. User Facility or Importer Name/Address			
4. Contact Person		5. Phone Number	
6. Date User Facility or Importer Received Report of Event (month/year)		7. Type of Report <input type="checkbox"/> Initial <input type="checkbox"/> Follow-up if _____	8. Date of This Report (month/year)
9. Approximate Age of Device		10. Event Problem Codes (Refer to coding manual)	
		Patient Code _____ Device Code _____	
11. Report Sent to FDA? <input type="checkbox"/> Yes (month/year) <input type="checkbox"/> No		12. Location Where Event Occurred <input type="checkbox"/> Hospital <input type="checkbox"/> Outpatient Diagnostic Facility <input type="checkbox"/> Home <input type="checkbox"/> Ambulatory Surgical Facility <input type="checkbox"/> Nursing Home <input type="checkbox"/> Outpatient Treatment Facility <input type="checkbox"/> Other _____ (describe)	
13. Report Sent to Manufacturer? <input type="checkbox"/> Yes (month/year) <input type="checkbox"/> No			
14. Manufacturer Name/Address			
G. ALL MANUFACTURERS			
1. Contact Office - Name/Address (and Manufacturing Site for Devices)		2. Phone Number	
3. Report Source (check all that apply) <input type="checkbox"/> Foreign <input type="checkbox"/> State <input type="checkbox"/> Literature <input type="checkbox"/> Consumer <input type="checkbox"/> Health Professional <input type="checkbox"/> User Facility <input type="checkbox"/> Company Representative <input type="checkbox"/> Distributor <input type="checkbox"/> Other _____			
4. Date Received by Manufacturer (month/year)		5. FDA ID # MD # PL #	
6. PRECIS, QRS Protocol		Pre-1988 <input type="checkbox"/> Yes OTC Product <input type="checkbox"/> Yes	
7. Type of Report (check all that apply) <input type="checkbox"/> 5-day <input type="checkbox"/> 15-day <input type="checkbox"/> 30-day <input type="checkbox"/> Periodic <input type="checkbox"/> Initial <input type="checkbox"/> Follow-up if _____		8. Advance Event Time(s)	
9. Manufacturer Report Number			

H. DEVICE MANUFACTURERS ONLY	
1. Type of Reportable Event <input type="checkbox"/> Death <input type="checkbox"/> Serious Injury <input type="checkbox"/> Malfunction <input type="checkbox"/> Other _____	
2. If Follow-up, What Type? <input type="checkbox"/> Correction <input type="checkbox"/> Additional Information <input type="checkbox"/> Response to FDA Request <input type="checkbox"/> Device Replacement	
3. Device Provided by Manufacturer? <input type="checkbox"/> Not Related to Manufacturer <input type="checkbox"/> Yes <input type="checkbox"/> Evaluation Summary Attached <input type="checkbox"/> No (Attach page for incident report(s) or provide code)	
4. Device Manufacture Date (month/year)	
5. Labeled for Single Use? <input type="checkbox"/> Yes <input type="checkbox"/> No	
6. Evaluation Codes (Refer to coding manual)	
Method _____ Results _____ Conclusions _____	
7. If Remedial Action Initiated, Check Type <input type="checkbox"/> Recall <input type="checkbox"/> Field Notice <input type="checkbox"/> Repair <input type="checkbox"/> Rejection <input type="checkbox"/> Replace <input type="checkbox"/> Patient Monitoring <input type="checkbox"/> Rebuilding <input type="checkbox"/> Modification <input type="checkbox"/> Substitution <input type="checkbox"/> Other _____	
8. Usage of Device <input type="checkbox"/> Initial type of Device <input type="checkbox"/> Repeat <input type="checkbox"/> Unknown	
9. If action reported to FDA under 21 USC 3605 (f), list incident(s) (attach report(s) if available)	
10. <input type="checkbox"/> Additional Manufacturer Name(s) and Address	11. <input type="checkbox"/> Corrected Date

The public reporting burden for this collection of information has been estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering the required data, reviewing the collected data, completing and reviewing the collection of information, and sending the collection of information to the agency.

Department of Health and Human Services

OSMR Statement  
This information is not to be used for commercial purposes.

# MedWatch Form Form FDA 3500A

## Page 2

### Section G\*

(Sections F and H are  
for device  
manufacturers)

G. ALL MANUFACTURERS	
1. Contact Office - Name/Address (and Manufacturing Site for Devices)	
2. Phone Number	
3. Report Source (Check all that apply)	
<input type="checkbox"/> Foreign	
<input type="checkbox"/> Study	
<input type="checkbox"/> Literature	
<input type="checkbox"/> Consumer	
<input type="checkbox"/> Health Professional	
<input type="checkbox"/> User Facility	
<input type="checkbox"/> Company Representative	
<input type="checkbox"/> Distributor	
<input type="checkbox"/> Other: _____	
4. Date Received by Manufacturer (mo/day/yr)	5. (A)NDA # _____
	IND # _____
	PLA # _____
6. If IND, Give Protocol #	Pre-1938 <input type="checkbox"/> Yes
	OTC Product <input type="checkbox"/> Yes
7. Type of Report (Check all that apply)	8. Adverse Event Term(s)
<input type="checkbox"/> 5-day	
<input type="checkbox"/> 10-day	
<input type="checkbox"/> Initial	
<input type="checkbox"/> 15-day	
<input type="checkbox"/> Periodic	
<input type="checkbox"/> Follow-up # _____	
9. Manufacturer Report Number	

\* Will be Section I in the Revised 3500A

<http://www.fda.gov/medwatch/getforms.htm>

USE BLACK INK

# Where do I submit the MedWatch form?

- **Send 2 copies of each MedWatch report to:**

Center for Biologics Evaluation and Research

HFM-210

1401 Rockville Pike, Suite 200N

Rockville, MD 20852



# Common MedWatch Problems

## Device Section filled out

A. PATIENT INFORMATION <small>Section A - Help</small>			
1. Patient Identifier ADD	2. Age at Time of Event 10 or Date of Birth:	3. Sex <input checked="" type="checkbox"/> Female <input type="checkbox"/> Male	4. Weight 130 lbs or kg
B. ADVERSE EVENT OR PRODUCT PROBLEM <small>Section B - Help</small>			
1. <input checked="" type="checkbox"/> Adverse Event and/or <input type="checkbox"/> Product Problem (e.g., defect/malfunction)			
2. Outcomes Attributed to Adverse Event (Check all that apply)			
<input type="checkbox"/> Death (mortality)		<input type="checkbox"/> Disability	
<input type="checkbox"/> Life-threatening		<input type="checkbox"/> Congenital Anomaly	
<input type="checkbox"/> Hospitalization - initial or prolonged		<input checked="" type="checkbox"/> Required Intervention to Prevent Permanent Impairment/Damage	
<input type="checkbox"/> Other:			
3. Date of Event (month/year) 11/30/2004	4. Date of This Report (month/year) 12/02/2004		
5. Describe Event or Problem			
25 yo woman underwent ACL transplant with tibialis tendon on 11/09/2004. She developed septic arthritis on 11/23/04 and was started on antibiotics. Symptoms worsened and she required explantation on 11/30/04.			
6. Relevant Tests/Laboratory Data, including Dates			
Wound culture 11/27/04. Staph aureus			
7. Other Relevant History, including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)			
C. SUSPECT MEDICATION(S) <small>Section C - Help</small>			
1. Name (Give labeled strength & manufacturer, if known)			
#1			
#2			
2. Dose, Frequency & Route Used		3. Therapy Dates (If antitumor, give duration) (month/day/year)	
#1		#1	
#2		#2	
4. Diagnosis for Use (Indication)		5. Event Abated After Use Stopped or Dose Reduced?	
#1 ACL repair		#1 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply	
#2		#2 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply	
6. Lot # (if known)	7. Exp. Date (if known)	8. Event Recurred After Reintroduction?	
#1	#1	#1 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply	
#2	#2	#2 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply	
9. MDC# (For product problem only)			
10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)			
D. SUSPECT MEDICAL DEVICE <small>Section D - Help</small>			
1. Brand Name JointSave Company			
2. Type of Device Tibialis Tendon			
3. Manufacturer Name, City and State JointSave Company Springfield, IL			
4. Model #	Lot #	5. Operator of Device	
	AS2004-1264	<input type="checkbox"/> Health Professional	
Catalog #	Expiration Date (month/day/yr)	<input type="checkbox"/> Lay User/Patient	
	6/3/05	<input type="checkbox"/> Other	
Serial #	Other #		
6. If Implanted, Give Date (month/day/yr) 11/09/2004		7. If Explanted, Give Date (month/day/yr) 11/30/04	
8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?			
<input type="checkbox"/> Yes <input type="checkbox"/> No			
9. If Yes to Item No. 8, Enter Name and Address of Reprocessor			
10. Device Available for Evaluation? (Do not send to FDA)			
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Returned to Manufacturer on: (month/day/yr)			
11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)			
Cephalexin 500 mg po bid 11/22-11/30/04			
E. INITIAL REPORTER <small>Section E - Help</small>			
1. Name and Address		Phone #	
John Dow 123 Main St Dallas, TX 12345		123-234-5678	
2. Health Professional?		3. Occupation	
<input type="checkbox"/> Yes <input type="checkbox"/> No			
4. Initial Reporter Also Sent			



Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or



# Common MedWatch Problems

No suspect  
product name

A. PATIENT INFORMATION		Section A - Help	
1. Patient Identifier APP	2. Age at Time of Event 25 or Date of Birth	3. Sex <input checked="" type="checkbox"/> Female <input type="checkbox"/> Male	4. Weight 130 lbs or kg
B. ADVERSE EVENT OR PRODUCT PROBLEM			
Section B - Help			
1. <input checked="" type="checkbox"/> Adverse Event and/or <input type="checkbox"/> Product Problem (e.g., defect/malfunction)			
2. Outcomes Attributed to Adverse Event (Check all that apply)			
<input type="checkbox"/> Death (mortality) <input type="checkbox"/> Life-threatening <input type="checkbox"/> Hospitalization - initial or prolonged <input type="checkbox"/> Disability <input type="checkbox"/> Congenital Anomaly <input checked="" type="checkbox"/> Required Intervention to Prevent Permanent Impairment/Damage <input type="checkbox"/> Other			
3. Date of Event (m/d/yyyy) 11/30/2004		4. Date of This Report (m/d/yyyy) 12/02/2004	
5. Describe Event or Problem			
<p>25 yo woman underwent ACL transplant with tibialis tendon on 11/09/2004. She developed septic arthritis on 11/22/04 and was started on antibiotics. Symptoms worsened and she required explantation on 11/30/04.</p>			
6. Relevant Tests/Laboratory Data, including Dates			
<p>Wound culture 11/27/04. Staph aureus</p>			
7. Other Relevant History, including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepato/bone dysfunction, etc.)			
<p></p>			
C. SUSPECT MEDICATION(S)		Section C - Help	
1. Name (Give labeled strength & manufacturer, if known)			
#1			
#2			
2. Dose, Frequency & Route Used		3. Therapy Dates (If antitumor, give duration; if toxic, for best estimate)	
#1		#1	
#2		#2	
4. Diagnosis for Use (Indication)		5. Event Altered After Use Stopped or Dose Reduced?	
#1 ACL repair		#1 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply	
#2		#2 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply	
6. Lot # (if known)	7. Exp. Date (if known)	8. Event Recurred After Reintroduction?	
#1	#1	#1 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply	
#2	#2	#2 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply	
9. NDC# (For product problems only)			
#1			
#2			
10. Concurrent Medical Products and Therapy Dates (Exclude treatment of event)			
D. SUSPECT MEDICAL DEVICE		Section D - Help	
1. Brand Name			
2. Type of Device			
3. Manufacturer Name, City and State JointCare Company Springfield, IL			
4. Model #	Lot #	5. Operator of Device	
	RE2004-1264	<input type="checkbox"/> Health Professional	
Catalog #	Expiration Date (m/d/yyyy)	<input type="checkbox"/> Lay/Use/Patient	
	6/5/05	<input type="checkbox"/> Other	
Serial #	Other #		
6. If Implanted, Give Date (m/d/yyyy)	7. If Explanted, Give Date (m/d/yyyy)		
11/09/2004	11/30/04		
8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?			
<input type="checkbox"/> Yes <input type="checkbox"/> No			
9. If Yes to Item No. 8, Enter Name and Address of Reprocessor			
10. Device Available for Evaluation? (Do not send to FDA)			
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Returned to Manufacturer on: (m/d/yyyy)			
11. Concurrent Medical Products and Therapy Dates (Exclude treatment of event)			
Cephalexin 500 mg po bid 11/22-11/30/04			
E. INITIAL REPORTER		Section E - Help	
1. Name and Address		Phone #	
John Doe 123 Main St Dallas, TX 12345		222-234-2456	
2. Health Professional?		3. Occupation	
<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No		Other Healthcare Profes	
4. Initial Reporter Also Sent Report to FDA		5. Initial Reporter Also Sent Report to FDA	
<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Unk.		<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Unk.	



Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

FORM FDA 3600A (8/03)

# Common MedWatch Problems

Nonspecific product  
name

No manufacturer  
name

C. SUSPECT MEDICATION(S)		Section C - Help
1. Name (Give labeled strength & mfr/labeler, if known)		
#1 Tissue		
#2		
2. Dose, Frequency & Route Used		3. Therapy Dates (If unknown, give duration from/to (or best estimate))
#1		#1 11/09/2004
#2		#2 11/20/2004
4. Diagnosis for Use (Indication)		5. Event Abated After Use Stopped or Dose Reduced
#1 ACL repair		#1 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know
#2		#2 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know
6. Lot # (if known)	7. Exp. Date (if known)	8. Event Reappeared After Reintroduction?
#1	#1	#1 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know
#2	#2	#2 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know
9. NDC# (For product problems only)		
-		
10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)		

BRAVO!

U.S. Department of Health and Human Services

**MEDWATCH**

The FDA Safety Information and  
Adverse Event Reporting Program

For use by user-facilities,  
importers, distributors and manufacturers  
for MANDATORY reporting

General Instructions

Page 1 of 1

MF Report #
UFI Report #
FDA Use Only

<b>A. PATIENT INFORMATION</b> <a href="#">Section A - Help</a>			
1. Patient Identifier APD	2. Age at Time of Event or Date of Birth 35 <input checked="" type="checkbox"/> Yes In confidence	3. Sex <input checked="" type="checkbox"/> Female <input type="checkbox"/> Male	4. Weight 110 <input type="checkbox"/> lbs or <input type="checkbox"/> kgs
<b>B. ADVERSE EVENT OR PRODUCT PROBLEM</b> <a href="#">Section B - Help</a>			
1. <input checked="" type="checkbox"/> Adverse Event and/or <input type="checkbox"/> Product Problem (e.g., defect/malfunction)			
2. Outcomes Attributed to Adverse Event (Check all that apply) <input type="checkbox"/> Death (mortality) <input type="checkbox"/> Life-threatening <input type="checkbox"/> Hospitalization - initial or prolonged <input type="checkbox"/> Disability <input type="checkbox"/> Congenital Anomaly <input checked="" type="checkbox"/> Required Intervention to Prevent Permanent Impairment/Damage Other:			
3. Date of Event (m/d/yyyy) 11/30/2004		4. Date of This Report (m/d/yyyy) 12/02/2004	
5. Describe Event or Problem 35 yo woman underwent ACL transplant with tibialis tendon on 11/09/2004. She developed septic arthritis on 11/23/04 and was started on antibiotics. Symptoms worsened and she required explantation on 11/30/04.			
6. Relevant Tests/Laboratory Data, including Dates Mound culture 11/27/04: Staph aureus			
7. Other Relevant History, including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatobiliary dysfunction, etc.)			

<b>C. SUSPECT MEDICATION(S)</b> <a href="#">Section C - Help</a>	
1. Name (Give labeled strength & manufacturer, if known) #1 Tibialis Tendon Jointwave Company #2	
2. Dose, Frequency & Route Used #1 #2	3. Therapy Dates (If known, give duration) #1 11/09/2004 #2 11/30/2004
4. Diagnosis for Use (Indication) #1 ACL repair #2	5. Event Abated After Use Stopped or Dose Reduced? #1 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply #2 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply
6. Lot # (If known) #1 R22004-1254 #2	7. Exp. Date (If known) #1 09/05 #2
8. Event Reappeared After Reintroduction? #1 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply #2 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply	
9. NDC# (For product problems only) - -	
10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event) Cephalexin 500 mg po bid 11/23-11/30/04	
<b>D. SUSPECT MEDICAL DEVICE</b> <a href="#">Section D - Help</a>	
1. Brand Name	
2. Type of Device	
3. Manufacturer Name, City and State	
4. Model # Catalog # Serial #	5. Operator of Device <input type="checkbox"/> Health Professional <input type="checkbox"/> Lay User/Patient <input type="checkbox"/> Other: 7. If Explanted, Give Date (m/d/yyyy)
8. If Explanted, Give Date (m/d/yyyy)	
9. Is this a Single-use Device that was Reprocessed and Reused on a Patient? <input type="checkbox"/> Yes <input type="checkbox"/> No	
10. Device Available for Evaluation? (Do not send to FDA) <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Returned to Manufacturer or (m/d/yyyy)	
11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)	
<b>E. INITIAL REPORTER</b> <a href="#">Section E - Help</a>	
1. Name and Address John Doe 123 Main St Dallas, TX 75245	
Phone # 123-234-3456	

PLEASE TYPE OR USE BLACK INK